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Statistical Analysis Plan

Truvada® vs. Genvoya®

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Demographic, behavioral, clinical, and laboratory data will be collected from the screening clinical assessment, the study entry physical examination and screening laboratory tests, and rectal biopsy visits.

Median (range) drug levels will be calculated at baseline and each of the protocol specified follow-up time points. Differences in median drug levels between baseline and study visit follow-up visits will be analyzed with non-parametric Wilcoxon-signed rank tests. A p-value of <0.05 will be considered significant.